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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,872	03/24/2004	Mian Ying Wang	10209.476	6611

21999 7590 03/17/2008

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,872	WANG ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/14/07 has been entered.

Claims 1-13 are pending in the application.

Claims 12-13 remain withdrawn from examination on the merits, being elected without traverse because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement of 4/6/06.

Claims 1-11 were examined on their merits with regard to the elected species of *Morinda citrifolia* leaf extract.

It is noted that *Morinda citrifolia* may be referred to herein as 'MC'.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 103

Claims 1-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly (US 6,340, 703) in view of Chang et al. (US 2006/00996900 A1) in view of Davis (US 5,708,038) in view of Elkins, R. (1998) in view of Flockhart et al. (WO 9307901 A1) for the reasons set forth keenly in the previous Office action.

Applicant's arguments were fully considered, but not found persuasive.

Initially, Applicants reiterate the Graham factual inquiries and reassert the 103(a) statute (p. 5, Remarks). Applicants contend that the Examiner has not set forth a prima facie case of obviousness under the 103(a) statute in light of the Graham factual inquiries because Applicants assert that the cited prior art of record does not teach every limitation in the claimed invention (p. 6, Remarks). Applicants further contend that the claimed ranges of MC provide for an unexpected result, which obviates this outstanding rejection:

> However, the claimed invention involves ranges, which produce unexpected results. In particular, at higher concentrations administration of Morinda citrifolia leaf extract caused inhibition of enzyme induction as noted on page 23 of the originally filed specification. In this non-limiting example, the Morinda citrifolia leaf extract exerted a significant induction of alcoline [sic] phosphotase [sic], and maximum effect was achieved at 0.3 ml/ml (representing 30 mg dry leaves/ml); higher concentrations caused an inhibition of enzyme induction. The unexpected

> result that increased concentrations of Morinda citrifolia leaf extracts result in an inhibition of enzyme induction is not taught in the cited references (see p. 6, Remarks).

While Applicants' arguments in contention of an unexpected result was carefully considered, such contentions are deemed mere allegations absent any side-by-side comparison with beta-sitosterol, a compound already known in the art to be inherent in MC leaf and additionally known to possess estrogenic activity as disclosed by Elkins and Davis. Absent such verifiable proof, Applicant's assertions are unsubstantiated. It is additionally pointed out that in the event that Applicants do convincingly verify an unexpected result, the claims must be commensurate in scope with such results.

Applicants additionally argue:

> Chang discloses only that rutin is a flavanoid glycoside comprised of quercetin and a sugar, rutinose, and that many beneficial health effects of rutin have been demonstrated. Chang fails to disclose the claimed ranges of rutin and quercetin, and fails to teach the unexpected result that higher concentrations cause an inhibition of enzyme induction.
> Kelly discloses merely that it is known for example that other compounds present in ligunes such as flavanoids (e.g. quercetin, luteolin, kaempferol and lignans) also are estrogenic. Kelly likewise fails to disclose the claimed ranges of quercetin and rutin, and fails to teach o fairly suggest the unexpected result that higher concentrations of leaf extract result in inhibition of enzyme induction.

While Applicant argues that Chang and Kelly fail to disclose the ranges of rutin and quercetin, it was keenly established in the previous Office action that the routine adjustment of amounts of known, effective ingredients to incorporate into neutraceutical/pharmaceutical preparations was considered *prima facie* obvious to the ordinary artisan at the time the invention was made. Applicant's arguments that Chang fails to teach "...the unexpected result that higher concentrations cause an inhibition of

enzyme induction" is unsubstantiated " because first, Applicants have not shown that higher amounts of rutin or quercetin have an unexpected result over the rutin and quercetin of the prior art. Applicants' arguments in contention of an unexpected result on page 6 of the remarks are associated with Morinda citrifolia leaf extract, and not with amounts of quercetin or rutin which may provide for an unexpected result. Thus, there is no evidence of record to indicate that the claimed ranges of quercetin or rutin provide for any unexpected estrogenic activity. Also, it is reminded that A rejection under 35 U.S.C. ' 103 based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention. Ex parte Raychem Corp, 17 U.S.P.Q. 2d 1417. Thus, the ordinary artisan at the time the invention was made, with the aforementioned references before him/her would have been motivated to combine the Instantly claimed ingredients because they were all known to have estrogenic effects. Thus, the ordinary artisan would have had a reasonable, predictable degree of success in producing the claimed invention; and further, with the prior knowledge that both quercetin and rutin were estrogenic, the adjustment of concentrations of each of rutin and quercetin in neutraceutical/pharmaceutical preparations would have been well within the purview of the ordinary artisan at the time the invention was made.. "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton *KSR* 127S. Ct. at 1742.

. Further, In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants additionally argue:

> Davis discloses only that estrogens have been isolated from a number of plant sources and that to date, only three sterols having mild estrogenic activity have been isolated. Importantly, Davis teaches that the estrogenic activity of plant sterols has been estimated to be approximately 1/400 of that recorded for estrodile [*sic*]. Accordingly, not only does Davis fail to disclose the claimed ranges of quercetin and rutin, and the unexpected result that higher concentrations cause inhibition of enzyme induction, but Davis additionally teaches away from the use of plant sterols in favor of estrodile [*sic*], as the plants produce only a mild estrogenic effect, approximately 1/400 of that recorded for estrodile [*sic*]. The magnitude of the unexpected result, as indicated in the table on page 23 of the present invention, is therefore significant and non- obvious in light of the art cited. Accordingly, Applicant respectfully submits the claims provided herein, are not anticipated or rendered obvious by the cited references. Verdegall Bros. v. Union Oil Co. of California, 814 F. 2d 628, 631 (Fed. Cir. 1987) (p. 7, Remarks)

However, it appears that Applicants have misinterpreted the teachings of Davis. The crux of the Davis patent is to deliver an extract of aloe vera which contains beta-sitosterol, which in the Davis patent 1) they specifically refer to as 'sitosterol':

> The present invention provides a method for using Aloe vera as a biological vehicle for the delivery of drugs. In one embodiment Aloe vera is used as a biological vehicle to deliver the estrogen, .beta.-estradiol and the androgen, testosterone propionate. The present invention also provides a method of treating symptoms and diseases mediated by hormonal deficiencies or amenable to treatment by hormones using Aloe vera as a biological vehicle (see abstract)

> The estrogens are a group of hormones which promote proliferation and growth of specific cells in the body and are responsible for the development and maintenance of secondary female sex characteristics. The estrogens are mainly responsible for cellular proliferation and growth of the tissues of the

> sexual organs and of other tissues related to reproduction. Estrogens also participate in the menstrual cycle. Naturally occurring estrogens, such as .beta.-estradiol, estrone and estriol, are steroids produced primarily by the ovaries. **.beta.-Estradiol (referred to herein as estradiol) is involved in the maturation and cyclic function of accessory sex organs and the development of the duct system in mammary glands** (see col. 2, lines 21-38, emphasis added)

Therefore, while Davis discloses the advantageous use of estradiol over other plant sterols, it is clear that 'estradiol' is 'beta-estradiol', the same compound found in MC leaf. Further, as Applicants state, Davis does not specifically teach rutin or quercetin or any other specific plant sterols. Thus, Davis does not 'teach away' from the use of other plant sterols such as rutin or quercetin in any pharmaceutical preparation or their own preparation as asserted by Applicants on pp. 7-8 of the Remarks. On the contrary; Davis is merely reporting the advantageous effects of beta-sitosterol which is not deemed to negate any positive estrogenic effects innately possessed by quercetin or rutin which were already known in the art:

> **Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments**. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition **does not become patentable simply because it has been described as somewhat inferior to some other product for the same use**." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (See, MPEP § 2123, emphasis added)

Thus, Applicants' arguments pertaining to Davis 'teaching away' from the claimed invention are not accepted

Further, with regard to the arguments pertaining to Davis, Applicant is again imparting piecemeal analysis to the references; while the rejection is made in view of the combination of the references. It is reiderated that an unexpected result has not been established as Applicants contend.

> [If]… there are [a] finite number of identified, predictable solutions, [a] person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007.From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No Claims are allowed.

This is an RCE of applicant's earlier Application No. 10/808,872. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

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